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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/824,906

Applicant(s)

GRUENBERG, MICHEAL L.

Examiner

Ron Schwadron, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8,9,12 and 71-101 is/are pending in the application.
- 4a) Of the above claim(s) 71-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8,9 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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1. Applicant's election without traverse of Group I in the paper filed 11/7/2003 is acknowledged.
2. Applicant's election of the species IL-4/antiCD3 and antiCD28 antibody/CD4+ T cells in the paper filed 11/7/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 71-101 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 11/7/2003.
4. Claims 1,3-5,8,9,12 are under consideration.
5. Applicant needs to update the status of all US patent applications disclosed in the specification.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 1,3-5,8,9,12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "one or more agents" in claim 1. The various pages of the specification referred to in paragraph 1, page 8 of the paper filed 11/7/2003 do not disclose the instant limitation.

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Original claim 53 discloses use of IL-4 with anti-IL-12 monoclonal antibody and/or antiIFN-gamma monoclonal antibody, but does not disclose the scope of the claimed invention which encompasses use of antibodies other than monoclonal antibodies in combination with IL-4. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

There is no support in the specification as originally filed for the recitation of "do not require IL-2" in claim 5. The various pages of the specification referred to in paragraph 1, page 8 of the paper filed 11/7/2003 do not disclose the instant limitation. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

There is no support in the specification as originally filed for the recitation of "homogeneous population of Th2 cells comprises greater than about 50% Th2 cells." in claim 4. Regarding the specification, page 40, the quoted passage defines "substantially homogeneous" in terms of greater than about 50% of one cell type, but said definition is not applied to the term "homogeneous" per se. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 4 recites the limitation "homogeneous" in line 2. There is insufficient antecedent basis for this limitation in the claim because claim 1 recites "homogenous", not homogeneous.

10. Regarding priority to parent application 60/044693 for the purposes of prior art, for the same reasons that the claimed inventions constitute new matter, the claimed inventions are not entitled to priority to parent application 60/044693 for the purposes of prior art. In addition, there is no disclosure in parent application 60/044693 of the method of claim 1 that recites "homogenous population of Th2 cells". There is no disclosure in parent application 60/044693 of the method of claim 1 that uses combinations of the agents recited in claim 1, part(b), lines 3 and 4. There is no disclosure in parent application 60/044693 of the method of claims 4 or 5. There is also

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no disclosure in parent application 60/044693 of the method of claim 8 which recites all of the particular antibodies and combinations recited in said claim.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1,3-5,8,9,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over June et al. (US Patent 6,352,694) in view of Hsieh et al. and Cracauer et al. (US Patent 4,804,628).

June et al. teach that Th2 cells can be produced and expanded using treatment of CD4<sup>+</sup> T cells with antiCD3 antibody and antiCD28 antibody (see column 30, penultimate paragraph). Said method does not use exogenous IL-2. June et al. teach that the CD4<sup>+</sup> cells used can be antigen specific (see column 30, first complete paragraph). The antiCD3 and antiCD28 antibodies taught by June et al. are mitogenic monoclonal antibodies (see Example 14). The cells can be further isolated or purified (see column 19). The starting material can be human T cells isolated from PBL (see column 19). The cells can be expanded to reach greater than 10<sup>10</sup> cells (see column 28, lines 1-5 and column 54 ). The cells are homogenous because June et al. teach that this method selectively expands Th2 cells (see column 30, penultimate paragraph). The antiCD3 and antiCD28 antibodies can be monoclonal antibodies (see column 5, last paragraph and column 7, first paragraph). June et al. do not teach that the cells are grown at the specific concentration recited in claim 1 or the addition of exogenous IL-4. Cracauer et al. teach hollow fiber bioreactors and the use of such hollow fiber bioreactors for efficiently growing larger numbers of cells in vitro (see columns 1-3) wherein concentrations of greater than 10<sup>8</sup> cells per ml are achieved (see column 5, last paragraph). Hsieh et al. teach that the addition of IL-4 to T cells in vitro favors the development of Th2 cells (see abstract). Hsieh et al. teach that IL-4 increases Th2 in a concentration dependent fashion (see Table 2). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the

claimed invention because June et al. teach that Th2 cells can be produced and expanded using treatment of CD4+ T cells with antiCD3 antibody and antiCD28 antibody wherein said method does not use exogenous IL-2 whilst Cracauer et al. teach hollow fiber bioreactors and the use of such hollow fiber bioreactors for efficiently growing larger numbers of cells in vitro wherein concentrations of greater than  $10^8$  cells per ml are achieved and Hsieh et al. teach that the addition of IL-4 to T cells in vitro favors the development of Th2 cells. One of ordinary skill in the art would have been motivated to do the aforementioned because Cracauer et al. teach hollow fiber bioreactors and that the use of such hollow fiber bioreactors for efficiently growing larger numbers of cells in vitro (see columns 1-3). One of ordinary skill in the art would have been motivated to do the aforementioned because Hsieh et al. teach that IL-4 increases Th2 in a concentration dependent fashion (see Table 2)

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:00am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RONALD S. SCHWADRON

PRIMARY EXAMINER

GROUP 1800 1600

Ron Schwadron, Ph.D.

Primary Examiner

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